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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,944	08/02/2001	Johnway Gao	BA4-089	9428

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,944

Applicant(s)

GAO ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 2, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This application filed August 2, 2001 is a continuation in part of application 09/632,314 filed August 4, 2000, now abandoned.

Applicant's amendment filed January 2, 2004, has been received and entered. Claims 1-7 are cancelled. Claims 8-29 have been added. Claims 8-29 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 have been cancelled obviating the rejection made under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Newly added claims do not recite nor require the use of ATCC 26076, therefore would not be subject to the rejection.

Claims 1-7 have been cancelled obviating the rejection made under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly added claims recite and

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encompass specific fragments of SEQ ID NO: 8, therefore would not be subject to the previous rejection regarding written description.

Newly added claims 8-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, newly added independent claims 8, 10, 18, 22 and 28 each recite a promoter comprising "at least nucleotides 1823 through 2147 of SEQ ID NO.: 8". It is noted that Applicants have not provided any indication for support of the newly added claims, and upon review of the specification Examiner can not find literal or figurative support for the specific range of 1823-2147 recited in the claims. The detailed description of the inventions describes the glucoamylase promoter of *S. castellii* (ATCC 26077) to be a total length of 2184 base pairs (page 6, line 10) and that the putative promoter region is within 1662 base pairs (page 6, line 11). promoter. A descriptive comparison of two different glucoamylase promoters from different yeast strains is made, (starting on page 6, line 23) and the specific sequences are provided in Figure 5, however neither of these provide literal nor figurative support for the range of 1823-2147 specifically recited in the claims. Finally, the analysis of the specific promoter constructs reduced to practice in the working examples through the use of specific primers also fails to provide figurative support for the specific range (primers used in Example 3, page 11). In addition, dependent claims recite the specific ranges of : "1148 through 2147 of SEQ ID NO.: 8"

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(claims 11, 15, 19 and 26); "485 through 2147" (claim 12) ; and the specific addition of "2148 through 2150" (claim 13), none of which find literal nor figurative support in the instant specification. It is noted that the remaining dependent claims do not recite the limitations discussed above, however they are included in the basis of the rejection because they encompass the new subject matter without providing further limitations that are supported by the present disclosure. Therefore, they have been included in the basis of the rejection.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6,528,636 B1 (Gao and Skeen).

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US Patent 6,465,635 B2 (Gao and Skeen).

Both patents are by inventors common to the instant application and are drawn to similar inventions to that instantly claimed. It is noted that the language of the newly added claims mirrors language previously found allowable in these patents, but are drawn to and encompass different promoter sequences.

Conclusion

No is claim allowed.

As noted previously, the claims are free of the art of record because the art fails to teach promoter specific sequences of the glucoamylase gene isolated from *Schwanniomyces castellii* deposited as ATCC 26077 as set forth in SEQ ID NO: 8. Dowhanick *et al.* (IDS reference) teach that *Schwanniomyces castellii* strains have tightly regulated glucoamylase promoters, and Dohmen *et al.* (IDS reference) teach that such sequences can be isolated and used in other cell types for the regulation of heterologous transgenes. However, the art of record fails to disclose any specific glucoamylase promoter sequence as set forth as SEQ ID NO: 8. or the sequence of *Schwanniomyces castellii* that is deposited as ATCC 26077.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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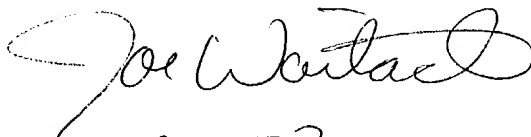
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



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